REMARKS

The Examiner is thanked for carefully reviewing the present application. The present amendment is in response to the Office Action mailed on December 4, 2008 regarding claims 1-9 and 11-19. The applicants have thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the references cited therein. The following remarks are believed to be fully responsive to the Office Action and render all claims at issue patentably distinguishable over cited references.

The first of such amendments to the specification paragraphs and abstract, is a typing error. Amendments to the specification paragraphs [0010]-[0030] and abstract, wherein some "filtering device" is amended as "filtering apparatus". Due to typing error that filtering apparatus was mistakenly typed in, and therefore referred to as filtering device. For example, as noted a mistake happened in paragraph [0014], where "in-vitro blood plasma lipids filtering apparatus" was mistakenly typed in instead of "in-vitro blood plasma lipids filtering device", in order to be distinct from "blood plasma lipids filtering device". In accordance and as reflected with support of the present invention figure representation that filtering apparatus and filtering device should be suitably distinct from each other. Hence the applicants amend related errors in the specification and abstract.

In addition, paragraph [0010] and [0014], the applicants also amend connection relationships, element functions and step order of all steps and elements. The amendment is done based on the support of originally filed specification, drawings and claims, especially Fig. 1.

The original abstract of the present invention is also being replaced with a new abstract.

Claims 1-5, 7-9, 11-16 and 18-19 are currently amended to clearly define the filtering method and the filtering apparatus of the present invention, while claim 6 is added into claim 1 and cancelled, claim 17 is added into claim 9 and cancelled, and claim 10 is previously cancelled, wherein "in-vitro blood plasma lipids filtering device" is amended to "in-vitro blood plasma lipids filtering apparatus" due to typing mistake, in order to be distinct from "blood plasma lipids filtering device". Further, the applicants also amend connection relationships and element

functions of all steps and elements based on the support of originally filed specification, drawings and claims, especially Fig. 1.

Applicants respectfully submit that no new matter has been added and that the originally filed specification, drawings and claims fully support the amendments.

Claim Rejections Under 35 U.S.C. 103 (a)

Examiner has rejected claims 1-8 as being unpatentable over **Bomberger '809** et al. (US 20030150809) in view of **Bomberger '776** et al. (US 20060000776). These grounds of rejection are respectfully traversed.

When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be **considered as a whole**;

(B) The references must be considered as a whole and must **suggest the desirability and thus the obviousness of making the combination**;

(C) The references must be **viewed without the benefit of impermissible hindsight vision afforded by the claimed invention**; and

(D) **Reasonable expectation of success** is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). (MPEP §2141)

If proposed modification would render the prior art invention being modified **unsatisfactory for its intended purpose**, then there is **no suggestion or motivation** to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (MPEP 2143)

The PTO further specifies in MPEP §2142 that:

The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no

obligation to submit evidence of nonobviousness.

As shown in Fig.1, claim 1 of the claimed invention recites that an in-vitro blood plasma lipids filtering method briefly comprises the steps of: collecting blood; separating blood plasma by the blood separating device, wherein the blood plasma enters the pre-filtered blood plasma bag including an automatic weight or volume detection device; flushing the blood plasma lipids filtering device by the saline solution treatment bag before filtering, wherein the flushed saline solution flows into the waste saline solution bag; controlling pressure of the separated blood plasma; filtering out lipids by the blood plasma lipids filtering device comprising multi-layers of thin film membranes, wherein at least a first film having filter aperture pores of about 0.3 to 0.65 microns and made of a lipid absorptive material for filtering out lipids of the separated blood plasma, a second film having filter aperture pores of about 0.3 microns for filtering out bacterium and chyle-lipoprotein, and a third film having filter aperture pore of about 0.2 microns and made of nylon as a base material for filtering out foreign particles generated from the first and second filtering processes, wherein the foreign particles include thin film wood-pulp material or adsorptive particles; collecting the filtered blood plasma by the post-filtered blood plasma bag; controlling the temperature of the filtered blood plasma; and feeding the filtered blood plasma back to the blood. After the amendment, **all connection relationships, element functions and step orders of all steps are limitations of claim 1.**

Regarding claim 1, **Bomberger '809** only discloses systems and methods **using multiple solvents** for the removal of lipids from fluids, wherein the **connection relationships, element functions and step orders of all steps and elements are obviously different from that of claim 1 of the present invention**. In Bomberger '809, the systems from input to output includes: HFC 18 of flushing step, sensor 96 of controlling temperature and pressure, DTCs 44 and 46 of filtering step, centrifuge 86 of separating step, step of returning plasma to patient **in turn**, so that the step order is exactly different from that of claim 1 of the present invention. It should be noted that the HFC 18 is element of an initial phase subsystem 12 (paragraph [0089]), which is actually used to remove lipids in the fluids (first extraction solvent), but lacks flushing or cleaning by saline

solution treatment bag. The sensor 96 is only used to monitor pressure and temperature (paragraph [0115]), but not "control" pressure and temperatures, wherein monitor and control is quite different. In addition, DTCs 44 and 46 are elements of an intermediate phase subsystem 14 (paragraph [0111]), which is actually used to receive the first mixture from HFC 18, fall the first mixture through the second extraction solvent (DiPE) and separate a portion (n-butanol) of the first extraction solvent (n-butanol and DiPE) from the fluid. Further, the centrifuge 86 is element of an intermediate phase subsystem 14 (paragraph [0089]), which is actually used to separate the first and second extraction solvents from the fluid in centrifuge 86, but the element functions and step orders thereof is different from the present invention. Besides, Bomberger '809 does **not teach a pre-filtered blood plasma bag including an automatic weight or volume detection device**, and **not disclose the structure and function of first film, second film and third film** of the present invention. Apparently, the systems and methods of Bomberger '809 is a multi-phase apparatus using multiple solvents and exists the foregoing differences from the present invention, while Bomberger '809 also does not have the motivation of changing the connection relationships, element functions and step orders of Bomberger '809.

Regarding claim 1, **Bomberger '776** only discloses hollow fiber contactor systems for removal of lipids from fluids, wherein a fluid source 14 may be composed of a plasmapheresis bag for containing a fluid (paragraph [0082]) and a saline fluid source 21 for containing a saline fluid (paragraph [0083]). However, Bomberger '776 does **not teach that fluid source 14 (pre-filtered blood plasma bag) includes an automatic weight or volume detection device**, and **not disclose the structure and function of first film, second film and third film** of the present invention. Apparently, the systems of Bomberger '776 is different from the present invention, and also does not have the motivation of changing the element structures and element functions of Bomberger '776.

Moreover, **Bomberger '776** does not suggest any desirability to combine **Bomberger '809**. Nevertheless, even assuming arguendo that a proper motivation for combination of the teaching of Bomberger '776 and '809, such combination would merely lead to systems and methods using

multiple solvents for the removal of lipids from fluids without the same connection relationships, element functions and step orders of all steps and elements, but does not produce Applicants disclosed and claimed invention in which an in-vitro blood plasma lipids filtering method comprising specific step order and uses a pre-filtered blood plasma bag including automatic weight or volume detection device and a blood plasma lipids filtering device comprising multi-layers of thin film membranes.

Accordingly, it is therefore respectfully submitted that the Office Action fails to establish a prima facie case of obviousness under §103 with respect to claim 1 of the claimed invention; and also fails to suggest the desirability for combining Bomberger '776 and '809 to teach claim 1 of the claimed invention.

Claim Rejections Under 35 U.S.C. 103 (a)

Examiner has rejected claims 6-7 as being unpatentable over **Bomberger '809** et al. (US 20030150809) in view of **Bomberger '776** et al. (US 20060000776), further in view of Matkovich et al. (US5252222). These grounds of rejection are respectfully traversed.

Regarding claim 6, all elements and function thereof are added into **amended claim 1**, and claim 6 is cancelled now. The amended claim 1 is unobvious over the combination of these prior arts of record. As cited by the Examiner, **Bomberger '809** discloses HFC 18 comprises hollow fiber 20 (first filter) having pores 26 between 3 nm (i.e. 0.003 um) and 300 um (i.e. 0.3 um) (paragraph [0101]). In addition, Examiner also states that **Matkovich** discloses a filter for parenteral systems and method of using thereof, however, the filter device and method of Matkovich is used to treat parenteral nutrient fluid **containing a lipid for administration (lipid is remained in parenteral nutrient fluid after filtering)**, but **not** applied to the technical filed for **removing lipids** from blood plasma (lipids is removed after filtering). Therefore, the filter device and method of Matkovich is in a technical field obviously different from the field of Bomberger '809 or the present invention. Actually, the filter device of Examples 3 and 5 of Matkovich includes a prefilter (second filter) with a pore rating of about 0.2 um and a hydrophilic nylon

membrane (third filter) with a pore rating of about 0.65 um (column 8, lines 32-41; column 7, lines 54-58), however the prefilter and hydrophilic nylon membrane are **not** used to remove lipid from parenteral nutrient fluid. Especially, the pore rating of about **0.2 um** of the prefilter (second filter) is different from the aperture pores of about 0.3 microns of second film claimed in amended claim 1 of the present invention, while the pore rating of about **0.65 um** of the hydrophilic nylon membrane (third filter) is quite different from the aperture pores of about 0.2 microns of third film claimed in amended claim 1 of the present invention. It should be noted that the pore size (0.003 um-0.3 um) of the hollow fiber 20 (first filter) of **Bomberger '809** is **smaller** than the pore rating (0.2 um) of the prefilter (second filter) of **Matkovich**, while the pore rating (0.2 um) of the prefilter (second filter) of Matkovich is **smaller** than the pore rating (0.65 um) of the hydrophilic nylon membrane (third filter) of Matkovich. In comparison, in amended claim 1 of the present invention, **the aperture pore (0.3 um–0.65 um) of the first film is greater than the aperture pore (0.3 um) of the second film, while the aperture pore (0.3 um) of the second film is greater than the aperture pore (0.2 um) of the third film**. Therefore, the pore size arrangement of Bomberger '809 and Matkovich is quite different from that of the present invention.

Moreover, **Matkovich** does not suggest any desirability to combine **Bomberger '809 and '776 due to different technical fields**. Nevertheless, even assuming arguendo that a proper motivation for combination of the teaching of Matkovich and Bomberger '776 and '809, such combination would merely lead to systems and methods using **three films with pore sizes arranging from small to large**, but does not produce Applicants disclosed and claimed invention in which an in-vitro blood plasma lipids filtering method comprising specific step order and uses a pre-filtered blood plasma bag including automatic weight or volume detection device and a blood plasma lipids filtering device comprising multi-layers of thin film membranes having **three films with pore sizes arranging from large to small**.

Accordingly, it is therefore respectfully submitted that the Office Action fails to establish a prima facie case of obviousness under §103 with respect to amended claim 1 (now added with claim 6) of the claimed invention; and also fails to suggest the desirability for combining

Matkovich and Bomberger '776 and '809 to teach amended claim 1 of the claimed invention.

In addition, insofar claims 2-5 and 7-8 depend upon claim 1. These claims add further limitations thereto. Thus, claims 2-5 and 7-8 of the present application are also unobvious over the prior art of record. Accordingly, Applicants respectfully request that the section 103(a) rejections be withdrawn.

Claim Rejections Under 35 U.S.C. 103 (a)

Examiner has rejected claims 9-16 as being unpatentable over **Bomberger '809** et al. (US 20030150809) in view of **Cham** (US 4895558), further in view of **Jacobsen** (US 5141493) in view of **Papillon**; Jean et al. (US 5348533). These grounds of rejection are respectfully traversed.

As shown in Fig.1, claim 9 of the claimed invention recites that an in-vitro blood plasma lipids filtering apparatus briefly comprises: a blood collecting device; a blood separating device; a pre-filtered blood plasma bag including an automatic weight or volume detection device; a peristaltic pump; a pressure control device; a blood lipids filtering device comprising multi-layers of thin film membranes, wherein at least a first film having filter aperture pores of about 0.3 to 0.65 microns and made of a lipid absorptive material for filtering out lipids of the separated blood plasma, a second film having filter aperture pores of about 0.3 microns for filtering out bacterium and chyle-lipoprotein, and a third film having filter aperture pore of about 0.2 microns and made of nylon as a base material for filtering out foreign particles generated from the first and second filtering processes, wherein the foreign particles include thin film wood-pulp material or adsorptive particles; a post-filtered blood plasma bag; a temperature control device; and a blood plasma feedback device. Further, a saline solution treatment bag is used for providing saline solution to flush the blood plasma lipids filtering device before the blood lipids filtering device filters out lipids of the separated blood plasma; and a waste saline solution bag is used for collecting the flushed saline solution from the blood plasma lipids filtering device during flushing the blood plasma lipids filtering device. After the amendment, **all connection relationships and element functions of all elements are limitations of claim 9.**

Regarding claim 9, **Bomberger '809** only discloses systems and methods **using multiple solvents** for the removal of lipids from fluids, wherein the **connection relationships and element functions of all elements are obviously different from that of claim 9 of the present invention**, as described above. Besides, Bomberger '809 does **not teach a pre-filtered blood plasma bag including an automatic weight or volume detection device**, and **not disclose the structure and function of first film, second film and third film** of the present invention. Apparently, the systems and methods of Bomberger '809 are different from the present invention, while Bomberger '809 also does not have the motivation of changing the connection relationships and element functions of Bomberger '809.

Regarding claim 9, **Cham** discloses an autologous plasma delipidation using a continuous flow system, and **Cham** only teaches that the delipidated plasma is drawn by the fluid replacement pump to be mixed with the red blood cells (a **replacement fluid** may be added to the plasma to overcome any loss in bulk of the plasma during the delipidation and separation steps)(column 8, lines 40-44) and the mixture passes through a vein monitor and is fed to a first disposable centrifugal separator where the blood is separated into red blood cells, plasma and **waste products** (the latter being collected in a **waste bag**) (column 8, lines 8-18). However, the function of the replacement fluid solution container and the waste bag for **adding fluid into blood or separating waste products from blood** is obviously different from the **flush function** of the saline solution treatment bag and waste saline solution bag of claim 9 of the present invention wherein the saline solution treatment bag is used for providing saline solution to **flush** the blood plasma lipids filtering device **before the blood lipids filtering device filters out lipids of the separated blood plasma**, while the waste saline solution bag is used for collecting the flushed saline solution from the blood plasma lipids filtering device **during flushing the blood plasma lipids filtering device**. Apparently, the autologous plasma delipidation of Cham is different from the present invention, while Cham also does not have the motivation of changing the element functions of Cham.

Regarding claim 9, **Jacosen** discloses a peritoneal dialysis system which is in a technical field obviously different from the field of Bomberger '809, Cham or the present invention. Jacosen

only teaches that a conventional **bubble trap device 20** connected to a conventional **dialyzer 24** (column 3, lines 21-34) and a **solution container 48** coupled into the primary circuit 4 (column 3, lines 43-54). However, the function of the bubble trap device 20 and the solution container 48 for peritoneal **dialysis system** is obviously different from the function of the pre-filtered blood plasma bag, blood lipids filtering device and post-filtered blood plasma bag of claim 9 of the present invention for in-vitro **blood plasma lipids filtering apparatus** wherein the pre-filtered blood plasma bag including an automatic weight or volume detection device is used for controlling the stop of the blood separating device or the blood collecting device, the blood lipids filtering device comprising multi-layers of thin film membranes having first film, second film and third film is used for filtering out lipids, bacterium and chyle-lipoprotein of the separated blood plasma and foreign particles, and the post-filtered blood plasma bag is used for collecting the filtered blood plasma. Apparently, the peritoneal dialysis system of Jacosen is different from the present invention, while Jacosen also does not have the motivation of changing the element functions of Jacosen.

Regarding claim 9, **Papillon** discloses a pheresis apparatus which is in a technical field obviously different from the field of Bomberger '809, Cham or the present invention. Papillon only teaches that a centrifuge 40 is comprised of a stationary part 12 and a rotatable part (bowl 10) (column 3-4, lines 65-9) and a digital weigher W2 is attached to plasma bag 18 to provide a signal to the processor 20 indicating the volume of fluid collected in the bags, but the weigher W2 and plasma bag 18 are in downstream of the centrifuge 40 which is not used for filtering out lipids from blood. Therefore, the function of the centrifuge 40 and the weigher W2 for **pheresis apparatus** are obviously different from the function of the blood lipids filtering device and the automatic weight or volume detection device of claim 9 of the present invention for in-vitro **blood plasma lipids filtering apparatus** wherein the automatic weight or volume detection device is installed in the pre-filtered blood plasma bag used for controlling the stop of the blood separating device or the blood collecting device, and the blood lipids filtering device comprising multi-layers of thin film membranes having first film, second film and third film is used for filtering out lipids, bacterium

and chyle-lipoprotein of the separated blood plasma and foreign particles. Apparently, the pheresis apparatus of Papillon is different from the present invention, while Papillon also does not have the motivation of changing the element functions of Papillon.

Moreover, **Cham, Jacobsen** and **Papillon** do not suggest any desirability to combine **Bomberger '809 due to different technical fields**. Nevertheless, even assuming arguendo that a proper motivation for combination of the teaching of Bomberger '809, Cham, Jacobsen and Papillon, such combination would merely lead to systems and methods for removing lipids from fluids or dialysis fluids without the same connection relationships, element functions and step orders of all steps and elements, but does not produce Applicants disclosed and claimed invention in which an in-vitro blood plasma lipids filtering method comprising specific step order and uses a pre-filtered blood plasma bag including automatic weight or volume detection device and a blood plasma lipids filtering device comprising multi-layers of thin film membranes.

Accordingly, it is therefore respectfully submitted that the Office Action fails to establish a prima facie case of obviousness under §103 with respect to claim 9 of the claimed invention; and also fails to suggest the desirability for combining Bomberger '809, Cham, Jacobsen and Papillon to teach claim 9 of the claimed invention.

In addition, insofar claims 11-16 and 18-19 depend upon claim 9. These claims add further limitations thereto. Thus, claims 11-16 and 18-19 of the present application are also unobvious over the prior art of record. Accordingly, Applicants respectfully request that the section 103(a) rejections be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that all pending claims as currently presented are in condition of allowance and hereby respectfully request reconsideration.

Respectfully submitted,

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